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| 10/507,253 | 03/21/2005 | John V Frangioni | BIDM-P01-012 | 4710 |

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| EXAMINER | |
|---|---|
| LEACH, CRYSTAL I | |
| ART UNIT | PAPER NUMBER |
| 3737 | |

| SHORTENED STATUTORY PERIOD OF RESPONSE | MAIL DATE | DELIVERY MODE |
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| 3 MONTHS | 04/06/2007 | PAPER |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/507,253 | FRANGIONI, JOHN V | |
| | Examiner | Art Unit | |
| | Crystal I. Leach | 3737 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-38* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-38* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *10 September 0204* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *9/19/2005 and 10/14/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

### *Information Disclosure Statement*

1. The Information Disclosure Statements (IDS) submitted on October 14, 2005, is in compliance with 37 CFR 1.97 and 1.98. The references therein have been considered.

### *Claim Objections*

2. Claims 5, 7-31 and 38 are objected to because of the following informalities:

On line 2 of claim 5, -- and -- needs to be inserted before "at".

Regarding claims 7-31 and 38, the form in which the dependent claims are written is not consistent. For example, in claim 12, applicant writes, "The system of any of claims 1-6" and then writes in claim 13, "The system of any of claims 1 through 12". To be consistent, all dependent claims referring to dependency of one of any sequentially listed claims should either all use a dash to denote the word "through" or use the actual word "through". Appropriate correction is required.

The following is a quotation of the sixth paragraph of 35 U.S.C. 112:

> An element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.

The means for performing the specified functions as outlined in claim 32 is not specifically stated in the written description of the specification. Examiner notes that for this reason, 35 U.S.C. 112, sixth paragraph has not been invoked in claim 32.

***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 1-17, 20-25, 28-34, 37 and 38 are rejected under 35 U.S.C. 102(e) as being anticipated by Imaizumi et al. (6,293,911).

5. Regarding claims 1 and 20, Imaizumi et al. teach a system comprising: a visible light source (61) capable of providing light over a range of wavelengths that includes one or more wavelengths of visible light (see col. 19, lines 8-9); an excitation light source (63) capable of providing light at one or more wavelengths outside the range of wavelengths of the visible light source, the one or more wavelengths selected to excite a fluorescent substance (see col. 20, lines 8-10), which emits one or more photons at an emission wavelength (see col. 19, lines 56-63); an electronic imaging device (col. 18, lines 61-64); an optical guide having a first end with a lens capable of capturing an image of a subject and a second end capable of coupling the image to the electronic imaging device (see col. 18, line 65 – col. 19, line 7 and col. 20, lines 30-35); and a filter (22) capable of coupling the visible light source and the excitation light source into the

optical guide, the filter being capable of reflecting some of the light provided by the visible light source and some of the light from the excitation light source toward the subject, the filter also being capable of transmitting some visible light from the subject captured by the lens toward the electronic imaging device, and being capable of transmitting the emission wavelength from the subject captured by the lens toward the electronic imaging device (col. 19, lines 21-22). See figure 21 and also the embodiments of figure 1 and figure 26.

Regarding claims 2-4, 20, 21, 32-34 and 37, Imaizumi et al. teach a system comprising: a visible light source (61) capable of illuminating a subject (see col. 18, lines 52-57), the visible light source providing a range of wavelengths including one or more wavelengths of visible light (see col. 19, lines 64-66); an excitation light source (63) capable of illuminating the subject, the excitation light source capable of providing an excitation wavelength that is not one of the one or more wavelengths of visible light (see col. 19, lines 59-61 and col. 20, lines 8-10); a fluorescent substance capable of being introduced into a circulatory system of the subject, the fluorescent substance being soluble in blood carried by the circulatory system and the fluorescent substance emitting photons at an emission wavelength in response to the excitation wavelength (see col. 19, lines 56-63); an electronic imaging device (see col. 18, lines 61-64) capable of capturing an image of a field of view that includes some portion of the subject and the circulatory system of the subject, the image including a first image obtained from the one or more wavelengths of visible light and a second image obtained from the emission wavelength (see Abstract, lines 7-13 and col. 20, lines 54-56 and lines 63-64);

and a display (6) capable of rendering the first image and the second image, the second image being displayed at a visible light wavelength (see Abstract, lines 13-17 and col. 22, lines 37-56) . See figure 21 and also the embodiments of figure 1 and figure 26.

Regarding claim 5, Imaizumi et al. teach that the one or more wavelengths of visible light from the visible light source does not include far-red light (see col. 19, line 64) and that at least one of the excitation light source and the emission wavelength include a far-red light wavelength (see col. 19, lines 59-60).

Regarding claim 6, Imaizumi et al. teach that the filter is a dichroic mirror (22) placed in the optical guide at a forty-five degree angle to a central axis of the optical guide (see figure 21 and col. 19, lines 21-22).

Regarding claims 7 and 8, Imaizumi et al. teach a second filter (62) that is capable of separating the emission wavelength from the range of wavelengths from the visible light source (see col. 20, lines 1-4), the emission wavelength being directed toward a first optical transducer of the electronic imaging device (see col. 20, lines 54-56) and the range of wavelengths from the visible light source being directed toward a second optical transducer of the electronic imaging device (see col. 20, lines 57-64).

Regarding claim 9, Imaizumi et al. teach a second filter (62) that is capable of separating the emission wavelength from the range of wavelengths from the visible light source (see col. 20, lines 1-4), the emission wavelength being directed toward a first optical transducer of the electronic imaging device (see col. 20, lines 54-56) and the range of wavelengths from the visible light source being directed toward a second optical transducer of the electronic imaging device (see col. 20, lines 57-64), wherein

the second optical transducer is capable of separately sensing at least each one of cyan, magenta, and yellow light intensities (see col. 13, lines 10-13 and col. 25, lines 12-14).

Regarding claim 10, Imaizumi et al. teach a second filter (23) capable of separating the emission wavelength from the range of wavelengths from the visible light source (see col. 19, lines 22-24), the emission wavelength being directed toward a first optical transducer of the electronic imaging device (see col. 20, lines 54-56) and the range of wavelengths from the visible light source being directed toward a second optical transducer of the electronic imaging device (see col. 20, lines 57-64), wherein the second filter includes a dichroic mirror (22) capable of reflecting the emission wavelength and transmitting the one or more wavelengths of visible light from the visible light source (see col. 20, lines 36-43 and lines 57-64).

Regarding claim 11, Imaizumi et al. teach a second filter (23) capable of separating the emission wavelength from the range of wavelengths from the visible light source (see col. 19, lines 22-24), the emission wavelength being directed toward a first optical transducer of the electronic imaging device (see col. 20, lines 54-56) and the range of wavelengths from the visible light source being directed toward a second optical transducer of the electronic imaging device (see col. 20, lines 57-64), wherein the second filter includes a dichroic mirror (22) capable of reflecting the one or more wavelengths of visible light from the visible light source and transmitting the emission wavelength (see col. 1, lines 11-12; col. 7, lines 1-7 and col. 25, lines 2-4).

Regarding claim 12, Imaizumi et al. teach a second filter (62) or (29) that shapes the wavelengths of the visible light source (see col. 19, lines 27-28 and col. 20, lines 1-7).

Regarding claim 13, Imaizumi et al. teach that the electronic imaging device includes at least one charge-coupled device (see reference characters "25"–"28" in figures 1, 21 and 25).

Regarding claims 14 and 15, Imaizumi et al. teach that the electronic imaging device includes a video camera (4A)/(5C) sensitive to visible light (see col. 18, lines 55-60 and col. 19, lines 20-53).

Regarding claims 16 and 17, Imaizumi et al. teach that the electronic imaging device captures a visible light image and an emission wavelength image (see col. 18 line 52 – col. 19, line 13), the system further comprising a processor (5C) capable of converting the emission wavelength image to a converted image having one or more visible light components, and combining or superimposing the converted image with the visible light image for display (see Abstract). See figure 21 and also the embodiments of figures 1 and 25 for similar components.

Regarding claims 22, 23, 25, 30, 31 and 38, Imaizumi et al. teach that the fluorescent substance labels at least one of an antibody, an antibody fragment, or a low-molecular-weight ligand that accumulates at a lesion, wherein the system is capable of visualizing the lesion, and wherein the fluorescent substance is soluble in blood, and the system is capable of visualizing a blood system (see col. 8, lines 1-25; col. 19, lines 56-63; col. 20, lines 26-29 and col. 28, lines 10-17). See figures 1 and 21.

Regarding claim 24, Imaizumi et al. teach that the display (6) is capable of rendering a second image superimposed on a first image (see Abstract).

Regarding claim 28, Imaizumi et al. teach that the display (6) is provided to a physician for use during a procedure, the procedure being at least one of a diagnostic procedure or a therapeutic procedure (see col. 2, lines 18-24 and col. 18, lines 52-60).

Regarding claim 29, Imaizumi et al. teach a surgical microscope (see col. 11, lines 36-46 and col. 27, lines 52-60).

***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claims 18 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Imaizumi et al. (6,293,911).

Imaizumi et al. teach combining and/or superimposing emission wavelength and visible light images (see Abstract). Imaizumi et al. also teach that each of the CCDs (25)-(28) produce 30 frame images per second (see col. 20, line 67).

Imaizumi et al. do not teach that the emission wavelength is captured at fifteen frames per second nor do Imaizumi et al. teach that the emission wavelength is converted to thirty frames per second for combination with the visible light image or that

the visible light image is converted to fifteen frames per second for combination with the emission wavelength image.

However, it would be obvious to one having ordinary skill in the art that the electronic imaging device as taught by Imaizumi et al. is capable of performing the overall function as desired in claims 18 and 19, that function being, combining both the visible light image and the emission wavelength image.

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to understand that the electronic imaging device taught by Imaizumi et al. is a functional equivalent of the electronic imaging device of claims 18 and 19 and that the use of an electronic imaging device like that taught by Imaizumi et al. is an improved system in that it permits combining of images without the necessity of converting image frames per second.

8. Claims 26 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Imaizumi et al. (6,293,911) in view of Benaron (6,167,297).

Imaizumi et al. do not teach that the fluorescent substance is capable of being sprayed onto the subject and that the fluorescent substance is one or more quantum dots.

However, Benaron teaches that a fluorescent substance capable of being sprayed onto a subject and a fluorescent substance comprising one or more quantum dots (see col. 5, line 61 – col. 6, line 4 and col. 6, lines 24-26).

It would have been obvious to one of ordinary skill in the art at the time of the invention to include a fluorescent substance capable of being sprayed onto a subject or

a fluorescent substance comprising one or more quantum dots in the invention taught by Imaizumi et al., in light of the teachings of Benaron, in order to provide a system with a variety of fluorescing means suitable for a variety of medical procedures.

9. Claims 35 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Imaizumi et al. (6,293,911) in view of Luiken (6,284,223).

Imaizumi et al. teach a method comprising: providing one or more wavelengths of visible light (see col. 18, lines 52-57 and see col. 19, lines 64-66); providing an excitation wavelength that is not one of the one or more wavelengths of visible fight (see col. 19, lines 59-61 and col. 20, lines 8-10); introducing a fluorescent substance into a subject (see col. 19, lines 56-63 and col. 20, lines 26-29), the fluorescent substance emitting photons at an emission wavelength in response to the excitation wavelength; providing a scope having a first optical path that directs the one or more wavelengths of visible light toward a subject, a second optical path that directs the excitation wavelength toward the subject, and a third optical path that directs an emission wavelength and the one or more wavelengths of visible light from the subject to an imaging device (see figure 21), wherein at least two of the first optical path, the second optical path, and the third optical path are coaxial (see figure 21); and displaying concurrently a visible light image of the subject and the emission wavelength image of the subject (see col. 18, lines 52-60 and Abstract, lines 7-17). Also see the Abstract.

Imaizumi et al. do not explicitly teach providing a laparoscope or making an incision in a body that includes the subject and directing the laparoscope into the incision so that the subject is within a field of view of the laparoscope.

Luiken teaches providing a laparoscope (see claim 20) or making an incision in a body that includes the subject and directing the laparoscope into the incision so that the subject is within a field of view of the laparoscope (see col. 3, lines 38-41).

It would have been obvious to one having ordinary skill in the art at the time of the invention to include a laparoscope or a method of making an incision in a body and directing the laparoscope into the incision in the invention of Imaizumi et al., in light of the teachings of Luiken, in order to enhance the utility and usability of the system.

***Conclusion***

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Sano et al. (6,099,466) teach a fluorescence diagnosis endoscope system; Koenig et al. (6,289,236) teach methods and apparatus for distinguishing inflamed and tumorous bladder tissue; Sekiguchi (4,821,117) teaches an endoscopic system for producing fluorescent and visible images; Hochman (6,671,540) teaches methods and systems for detecting abnormal tissue using spectroscopic techniques; Zeng et al. (6,898,458) teach methods and apparatus for fluorescence and reflectance imaging and spectroscopy and for contemporaneous measurements of electromagnetic radiation with multiple measuring devices; Nishioka et al. (4,807,026) teach an electronic image pickup device for endoscopes; and Freitag et al. (6,061,591) teach an arrangement and method for diagnosing malignant tissue by fluorescence observation; Hayashi (6,804,549) teaches a sentinel lymph node detection method and system therefor.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Crystal I. Leach whose telephone number is 571-272-5211. The examiner can normally be reached on Monday through Friday, 8 am - 4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 571-272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

CIL

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